

## II. REMARKS

### Formal Matters

Claims 1 and 12-16 are pending after entry of the amendments set forth herein.

Claims 1, 3, 12,-16, and 26 were examined and were rejected. Claims 4-9, 11, and 20-25 were withdrawn from consideration.

Claims 3-9, 11, and 20-26 are canceled without prejudice to renewal, without intent to acquiesce to any rejection, and without intent to surrender any subject matter encompassed by the canceled claims. Applicants expressly reserve the right to pursue any canceled subject matter in one or more continuation and/or divisional applications.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

### PTO SB-08A form

Applicants respectfully request that the Examiner initial and return the PTO SB-08A form submitted with the Information Disclosure Statement filed on October 28, 2003 in this application, thereby indicating that the reference cited therein has been reviewed and made of record.

### Examiner Interview

The undersigned Applicants' representative thanks Examiner Zara for the courtesy of a telephonic interview, which took place on December 15, 2003, and which was attended by Applicants' representative Paula A. Borden and Examiner J. Zara. During the interview, the rejection of certain claims under 35 U.S.C. §112, first paragraph, were discussed. It is the understanding of the undersigned Applicants' representative that the rejection of claims 1 and 12-16 will be withdrawn in view of certain references submitted in U.S. Patent No. 6,566,324, and the allowed claims of U.S. Patent No. 6,566,324.

### Rejection under 35 U.S.C. §112, first paragraph

Claims 1, 3, 12-16, and 26 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking adequate written description. Claims 1, 3, 12-16, and 26 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement.

Claims 3 and 26 are canceled without prejudice to renewal, thereby rendering the rejection of these claims moot.

Applicants provided experimental data showing that systemic delivery of a selective EGFR antagonist reduces airway goblet cell hyperplasia. Thus, those skilled in the art would reasonably expect that the same EGF-R antagonist or other EGF-R antagonists, when administered by other routes, e.g., via inhalation, would be efficacious, because administration by inhalation is administration directly at the site of the target cells. Accordingly, the instant claims are enabled with respect to various routes of administration.

At the request of the Examiner, Applicants provide herewith copies of references provided in related patent applications that issued as U.S. Patent Nos. 6,566,324 and 6,551,989. Takeyama et al. ((2001) *Am. J. Physiol. Lung Cell Mol. Physiol.* 280:L165-L172), a copy of which is provided herewith as Exhibit 1, shows discusses intratracheal instillation of a selective EGFR tyrosine kinase inhibitor in a dose-dependent fashion. Intratracheal instillation is an art-accepted mode of airway delivery in small animal studies, and is accepted in the field as a model of airway delivery by inhalation. Discussion of intratracheal instillation as a model of airway delivery by inhalation is provided in Sabaitis et al. ((1999) *J. Appl. Toxicol.* 19:133-140), Leong et al. ((1998) *J. Appl. Toxicol.* 18:149-160), and Ritz et al. ((1993) *Fund. Appl. Toxicol.* 21:31-37), copies of which references are provided herewith as Exhibits 2, 3, and 4, respectively.

Conclusion as to the rejections under 35 U.S.C. §112, first paragraph

Applicants submit that the rejection of claims 1, 3, 12-16, and 26 under 35 U.S.C. §112, first paragraph, has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.


### III. CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number UCSF085CIP.

Respectfully submitted,  
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